Written Statement of Terry Douglass

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Before the

Senate Committee on Commerce, Science, and Transportation

Subcommittee on Science, Technology, and Space

"Emerging Technologies in the New Millenium"

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Introduction

Chairman Frist and other distinguished Members of the Subcommittee, thank you for this opportunity to testify at this important hearing. My name is Terry Douglass, and I am president of CTI, Incorporated whose home offices are located on Innovation Drive along the Tennessee Technology Corridor between Knoxville and Oak Ridge, Tennessee. Knoxville is the home of The University of Tennessee, and Oak Ridge is the home of the Oak Ridge National Laboratory which makes the location of our headquarters midway between the two institutions significant because of the highly technical nature of our business. CTI is the worldwide commercial leader in providing products and services to the positron emission tomography (commonly referred to as PET) market. PET is a medical diagnostic imaging technology that provides unique and useful metabolic, biochemical, and functional information necessary to the diagnosis and treatment of patients with cancer, heart, and brain disorders.

The question which this Subcommittee asked me to testify about is: "What experiences has CTI encountered bringing positron emission tomography to market, and what incentives and barriers were created by the federal government?" I will attempt to answer that question by providing a history and description of PET and CTI from my perspective as it relates to the federal government, and then identify specific incentives and barriers as well as possible solutions.

Who Is CTI?

Our company exists to advance the quality of life of our customers, employees, and shareholders through technology, creativity, and innovation. We place high value on market understanding, customer satisfaction, the individual and the team, continuous improvement, creativity and innovation, technological strength and depth, and high integrity. Our mission is as follows:

Market and Customer Mission: Make PET a primary clinical modality and expand into other related markets by delivering high quality, innovative, efficacious, reliable solutions.

Human Resource Mission: Create an environment which encourages continuous growth and improvement, interdependent relationships, and community involvement.

Stakeholder Mission: Sustain a business that will continually increase stakeholder value.

CTI was founded in 1983 and currently employs about 250 employees located throughout the world. Our annual sales are about $100 million. Currently, our business is to provide a complete line of products and services for PET, and that is all that we do. Our principal office is in Knoxville, Tennessee; but in addition, we have employees located in over twenty other cities in the United States and three locations in Europe. Siemens Medical Systems, U.S. and Siemens, AG represent our PET scanner product line worldwide. CTI and its affiliates are the commercial leaders in PET technology. Our products and services are provided throughout the world; and in fact, we have greater sales outside the United States than inside. Many firsts in PET have resulted from innovations and technologies developed by our employees. As a result, we have maintained a market leadership position in all aspects of commercial PET. Other U.S. commercial companies in PET include General Electric, Picker Corporation, Mallinckrodt, PETNet Pharmaceutical Services, LLC, and ADAC Laboratories. Competing companies in PET are also located in Japan and Canada and in several European countries.

The History and Value of PET

PET was invented by Dr. Michael E. Phelps over 25 years ago at Washington University in St. Louis. I, and the company that I worked for at the time, E.G.&G. Ortec located in Oak Ridge, Tennessee, participated with Dr. Phelps in his invention of PET. The first ten years of the development and utilization of the PET technology was primarily in the development of instrumentation and in research in neurology, cardiology, and oncology. PET was, and still is, useful in producing new knowledge about metabolic, biochemical, and functional processes of our bodies in the healthy or diseased subject. Many significant scientific and medical discoveries have been made as a result of the use of PET, and new discoveries continue today. The most prestigious medical schools in America, Europe, and Asia have PET research and clinical programs, and the number continues to grow. In recognition of the value of PET, Dr. Phelps recently received the 1998 Enrico Fermi Presidential Award, the most prestigious scientific award in the United States, for “his invention of PET and his seminal contributions in its use in research and patient care in neurological disorders, cardiovascular disease and cancer” as stated by President Clinton. In addition, this month Dr. Phelps was elected to the National Academy of Sciences. A further verification of the value of PET has been the naming of the principal biochemical compound used in PET as the “molecule of the century” and a tag placed on PET as the

"the biological imaging technique of molecular medicine of the future".

What is unique about PET? Disease is a biological process and PET uniquely provides images of the biological basis of disease. In this way, PET differs from imaging techniques like CT, MRI, and ultrasound that examine the structural changes that typically occur at late stages of disease and can be nonspecific about the type of disease. Because of this difference and the fact that disease is fundamentally a biological process, PET routinely detects disease when the CT and MRI are normal. PET has been shown to be the most accurate imaging technique in detecting many neurological and cardiac diseases and cancers in their early stages, even in their asymptomatic, silent stages. In lung, colorectal, melanoma, lymphoma, breast, head and neck cancers, PET has been shown to provide more accurate detection and staging by 10 to 20% over conventional approaches; and PET changes and improves patient management in 15 to 30% of cases. As a result, PET reduces costs, primarily due to the elimination of other less accurate diagnostic tests and ineffective surgeries. PET reduces the occurrence of incorrect or delayed diagnosis that produces more complicated patient conditions and increases the cost of care. In regard to costs, the use of PET in lung and colorectal cancer would reduce costs by $200 million and $75 million respectively. For example, to understand this better, it is known that in lung cancer, approximately 20-30% of lung masses are determined "resectable" by current criteria and imaging techniques. However at surgery, 10% of the patients are found to have unresectable disease, and 14% of surgical patients die within a year because the disease was more extensive than indicated by the conventional diagnostic description. In addition, 30 to 40% of the biopsies of lung lesions performed are benign because CT and MRI are inaccurate in distinguishing between benign from malignant lesions. The use of a PET and CT strategy, in place of CT alone, would result in a cost savings of approximately $200 million per year in the U.S. due to avoided unnecessary surgical procedures (with no loss of life expectancy) and unnecessary biopsies. These are but a few examples of the many examples of the clinical and cost effectiveness of PET. Even if one took the more conservative position that there are no cost savings, the dramatic improvement that PET provides in health care to the American people would be a compelling reason for it use. Clinical research and clinical practice indicate that the result will be similar for many other cancers.

PET is the gold standard for determining whether a patient with coronary artery disease will benefit from revascularization. In Alzheimer's disease, PET accurately detects the disease in its most mild stages, when treatments are most effective and all other imaging techniques are normal. This is also the case in other forms of dementia, movement disorders, such as Parkinson's and epilepsy. These findings are supported by published data and have been established in medical practice.

It should be recognized that PET provides a new way of imaging, detecting, characterizing, and helping to improve the treatment of human disease. As stated above, the fundamental nature of disease is that it is a biological process and this is what PET uniquely images! Once one accepts this undeniable principle then the value of PET becomes clear. It also becomes clear that the importance of PET is not in one disease but

that it provides a fundamental and important new way to examine disease in general. PET is the imaging technique of Molecular Medicine that is occurring from merging modern biology and medicine.

Applications of PET

Some of the specific indications for which PET has been determined by the medical community, private insurers, and the Food and Drug Administration to be applicable are described in the following:

1. Applications of PET for imaging cancer patients.

Lung carcinoma - to differentiate benign from malignant solitary pulmonary nodules, to stage mediastinal and distant disease, and to monitor effectiveness of therapy.

Colorectal carcinoma - to detect colorectal carcinoma, to distinguish recurrent tumor from scar, and to stage patients with advanced disease.

Head and neck tumors - to detect primary head and neck tumors, to differentiate scar from tumor after therapy, and to detect metastatic disease.

Lymphoma - to detect and stage Hodgkin's and non-Hodgkin's lymphoma and to monitor response to therapy.

Malignant melanoma - to detect and stage malignant melanoma and to monitor response to therapy.

Hepatic carcinoma - to detect hepatic cancers and to monitor therapy.

Ovarian carcinoma - to detect and stage ovarian carcinoma and to assess response to therapy.

Breast carcinoma - to detect primary breast cancer in patients with breasts difficult to evaluate with mammography or breasts with implants, to determine the extent of disease in patients with breast cancer, and to monitor effectiveness of therapy.

Pancreatic carcinoma - to detect and stage pancreatic carcinoma.

Thyroid carcinoma - to image metastases of advanced thyroid carcinoma.

Musculoskeletal tumors - to detect primary and recurrent or residual musculoskeletal tumors and to monitor response to therapy.

2. Applications of PET for characterizing myocardial blood flow and viability.

   Coronary artery disease assessment - to detect coronary artery disease and to identify individual stenosed vessels from studies performed both at rest and during stress.

   Treatment of coronary artery disease - to identify changes in blood flow following angioplasty or coronary artery bypass grafting or pharmacologic interventions (for example, cholesterol lowering drugs.)

   Myocardial viability - to assess potential reversibility of an impairment in cardiac wall motion or left ventricular function for revascularization in chronic coronary artery disease.

   Acute myocardial infarction - to assess location and severity of myocardial infarction, benefit or thrombolytic therapy, need for mechanical revascularization and potential for salvaging injured myocardium.

   Assessment of risk for cardiac morbidity and mortality.

3. Applications of PET for brain imaging in various physiological and pathologic conditions:

   Brain tumor - to grade the degree of malignancy and to differentiate necrosis from persistent tumor after therapy.

   Seizure disorder - to determine sites of epileptogenic foci in patients with partial complex seizure disorder refractory to medication.

   Dementia - to characterize etiological cause of dementia and to differentiate dementia of the Alzheimer's type from other causes of dementia.

   Stroke - to determine the degree and extent of brain damage.

   Mental depression - to differentiate unipolar from bipolar depression and to differentiate chronic depression from Alzheimer’s disease.

   Behavior-metabolism relationship studies - to delineate normal function or deficits in specific brain function.

   Movement disorders - to differentiate movement disorder and assess response to medical and surgical therapy.

Prospects for the use of PET in additional applications in research and patient care are

very promising. New research and clinical applications are being developed continuously. One of the most exciting areas for the 21st century is the recent development of imaging gene expression in vivo with PET. This new technique holds the promise of making an important contribution to the new molecular medicine and may help in understanding the massive amounts of information coming out of the Human Genome Project and the impact it will have on patient care.

The Role of the United States Government in the Development of PET

The United States federal government was instrumental in the early development of PET through the funding of research and development at many of the major scientific and medical institutions in the U.S. The National Institutes of Health (NIH), the Department of Energy (DOE), the Department of Defense (DOD), and the National Science Foundation (NSF) played key investment roles in the development of PET. In addition, the U.S. government funded many commercial developments successfully through the Small Business Innovation Research (SBIR) programs. One estimate places the total direct investment of public federal funds in PET to exceed $2 billion. In many cases of funding by governmental agencies, the expectation has been that the PET technology would be commercialized and made generally available to the public. To date, PET is not generally available to the public. PET is paid for by most private insurers or by individual patient payment, but is withheld for the most part from patients covered under Medicare.

Making Clinical PET a Reality

In 1983, CTI was formed with the mission of "making clinical PET a reality". I, along with four other founders including Dr. Phelps, put all that we owned (and more) on the line and started up CTI. At that time, we believed that all we had to do was research and develop the right clinical PET products, properly market and sell those products, and PET would proliferate as a major diagnostic imaging modality. For the first five years of our existence, we pursued this approach. In about 1990, we begin to realize that there were other hurdles that would have to be overcome. These hurdles included the education of the physicians, patients, providers, and insurers, the further simplification and cost reduction of providing the PET by technology innovation, and regulatory and reimbursement issues.

For the next five years in the early nineties, the PET commercial entities, the medical institutions utilizing PET, and the individual PET proponents then pursued the development of solutions to these problems. We were successful in our education activities and in further simplifications and cost reductions of providing PET imaging through innovation and new technology. We were successful in gaining reimbursement from private insurers and from CHAMPUS, the insurer for the military. But we were not so successful in overcoming the U.S. government regulatory and reimbursement hurdles. In fact, we were not able to even define those hurdles as they seemed to change and grow

as time passed.

PET is not yet a clinical reality. For example, the number of PET studies in the United States this year will probably total less than 100,000. Compared to diagnostic procedures for other modalities, PET is miniscule. It is estimated that in the U.S. alone, there are 24 million CT studies, 18 million MR studies, and 14 million nuclear medicine studies performed per year. PET represents less than 0.2 % of the basic diagnostic imaging procedures, even though PET has demonstrated clear advantages.

Barriers Created for PET by the Federal Government

The PET community has had to face two difficult regulatory and reimbursement issues in attempting to bring this technology to clinical utility. The first has been the difficulty in gaining Food and Drug Administration (FDA) approval for the radiopharmaceuticals used in PET. The PET scanners and cameras have been and are approved medical devices by the FDA, and the process for approval and inspection of these devices has been reasonable generally. The problem has been with the approval process for PET radiopharmaceuticals. Due to their short half-life and the regional manufacturing and distribution requirements for PET radiopharmaceuticals, the conventional New Drug Application (NDA) and Good Manufacturing Process (GMP) procedures for large-scale centralized drug manufacturing cannot be applied to PET radiopharmaceuticals. But, nevertheless, the FDA pronounced that these procedures would apply, and the PET community attempted to comply. We tried to understand and apply the FDA NDA and GMP processes; but after many years of unbelievable effort and cost, we were able to get approval for only one compound at one institution for only one minor indication! Interestingly, an estimate has been made that over 2 million PET studies have been performed around the world, and there has not been a single adverse reaction reported. Thus, PET is not only an efficacious procedure but also a very safe one that has been carried out with good professional and manufacturing practices. Clearly, the FDA requirements that were imposed on the approval of PET radiopharmaceuticals were unworkable and unnecessary.

However, now the outcome with the FDA regulatory requirements appears to be moving toward a viable solution. Thanks for this positive movement goes to the direct involvement of the U.S. Congress who passed legislation in December, 1997 that moved the FDA to work with representatives from industry, academia, and patient advocacy groups in developing a workable regulatory method. The FDA Reform Act required that all PET radiopharmaceuticals in the U.S. Pharmacopoeia (USP) would have the legal equivalent of FDA approval until the new FDA regulations were implemented. The FDA has drafted new regulations that will be effective for PET and will issue broad approval for PET indications.

Further, many attempts were made with the Health Care Financing Administration (HCFA) to gain reimbursement for Medicare recipients. HCFA turned us down many times citing primarily the lack of FDA approval as the reason for denying Medicare

reimbursement for PET. Without Medicare reimbursement approval, most providers would not even consider making the PET technology available since much of their income is derived from Medicare. Further, many of the private insurers cite a new technology as "experimental" if Medicare does not pay and will not reimburse either.

The regulatory and reimbursement barriers that the PET community has faced has probably delayed the delivery of the PET technology to the general public by ten years or more. Lives have been lost, incorrect diagnosis and treatment has been made, and billions of dollars have been spent unnecessarily.

The Role of the United States Congress in Overcoming Barriers

As a result of the PET community's lack of success in overcoming the regulatory and reimbursement barriers, about five years ago, we sought help from the U.S. Congress. Fortunately, we found two strong advocates for PET in the U.S. Senate, Senator Ted Stevens from Alaska and Senator Bill Frist from Tennessee, our home state. Senator Stevens' advocacy was a result of 15 years of first-hand knowledge and experience that he had gained from his association with Dr. Phelps. And Senator Frist's support was a result of his using PET in his cardiac surgery practice at Vanderbilt University Medical Center. Interestingly, Senator Frist has authored several peer-reviewed papers in which PET was used.

A Newsline Commentary from "The Journal of Nuclear Medicine" dated March, 1999 written by Ms. Elizabeth Connell, Legislative Assistant to Senator Stevens provides excellent documentation on the involvement of the Congress and Senators Stevens and Frist with the regulatory and reimbursement issues that we have faced in PET. I will quote many of Ms. Connell's statements in describing the help that Congress has provided for the PET community.

The first congressional initiative in attempting to overcome these obstacles was to file legislation to require Medicare to pay for PET scans for a broad list of indications. Unfortunately, under congressional rules dictated by the Gramm-Rudman-Hollings Budget Act, a legislative proposal that is considered to have a "cost" to the federal government (including its Medicare program) must have "offsets" or savings in other government programs, so that it is considered "budget neutral." This is necessary in order for the new legislation to be passed. Those in the nuclear medicine community know that PET should represent a net savings to the Medicare program, because, for example, it can clearly identify and stage many cancers better than conventional diagnostic procedures. Thus, it can eliminate unnecessary surgeries, reduce the number of diagnostic procedures and otherwise demonstrate to clinicians the best, most effective mode of treatment for a patient. The Congressional Budget Office (CBO), however, has taken the unalterable position that any new item which Congress requires Medicare to cover is an added cost to the program. In the case of PET, CBO estimates for Medicare coverage, even for a limited list of indications, ranged upwards of $1 billion. Faced with this perceived huge

price tag, for a technology that many members of Congress were unfamiliar with, we were not successful with his initial legislation.

Regarding FDA matters, we were not successful in our efforts to have the FDA develop a realistic regulatory scheme for approving PET radiopharmaceuticals. The agency simply would not listen to us. They would not listen, that is, until the 1997 Congress got serious about legislation to reform the FDA. We were suddenly presented with an opportunity to have a major impact on this legislation. Working with allies including Senator Bill Frist on the Senate Labor and Human Resources Committee, Senator Stevens wrote an amendment to the legislation, which was accepted by the FDA Reform Committee, that completely exempted from FDA regulation those PET radiopharmaceuticals approved under the standards of the United States Pharmacopoeia (USP). The FDA reacted very negatively to this proposed amendment. It also brought Senator Ted Kennedy into the picture. Senator Kennedy is a supporter of PET but is an even stronger supporter of the authority of the FDA. His staff asked us if we would work with the FDA to see if a compromise solution could be worked out. It then occurred to Senators Stevens and Frist that a compromise might be built on a larger platform and should include HCFA reimbursement for PET as a "trade-off " for allowing the FDA to continue to regulate PET radiopharmaceuticals on a separate and rational basis. After months of negotiating a compromise, a provision was added to the FDA Reform Act which laid out the principles for developing a new regulatory system for PET radiopharmaceuticals. The provision takes into account the unique nature of these radiopharmaceuticals and requires the participation of the PET community in the drafting of new FDA rules for approval.

At the same time, Senator Stevens and his staff negotiated with the Department of Health and Human Services (HHS), which oversees HCFA, on Medicare reimbursement for PET. Senator Stevens personally talked with HHS Secretary Donna Shalala to gain her cooperation. The conclusion of these negotiations was the Secretary Shalala letter of November 3, 1997, to Senator Stevens setting out the terms of their agreement for Medicare reimbursement of PET for lung cancer, with review and reimbursement of other indications to follow over an 18-month period. A copy of this letter is attached. Senator Stevens announced the agreement two days later at a dinner in New York where he was honored by the Dana Foundation and its chairman, David Mahoney, another strong supporter of PET. We were all very optimistic and believed that finally we were successful in gaining Medicare reimbursement for PET.

What happened since that week in early November, 1997 represents an object lesson in the disconnect between good faith agreements made between principals and the implementation of those agreements by the bureaucracy of HCFA. It also tells us how much remains to be done before our task is finished. The catalogue of what went wrong with putting the Stevens/Shalala agreement into effect by January 1, 1998, is endless: The 45 days to "checks being cut" turned into a series of acrimonious negotiations with the HCFA staff, culminating in a "coverage policy" document that was faxed late in the evening of New Year's Eve 1997. Although the document provided reimbursement for PET, it contained very negative and restrictive language. Months passed before HCFA

issued a payment code and policy. Those first attempts at reimbursement resulted in PET payments as low as $200 in Florida!

Concerned that his agreement with Secretary Shalala had not been honored, Senator Stevens spoke again with Secretary Shalala in early May, 1998 and wrote her a letter dated May 8, 1998. That letter spelled out what had gone wrong with their agreement and requested that the Secretary agree to a modification of the November 3 letter so that the true spirit of their agreement could be fulfilled. Secretary Shalala agreed verbally to Senator Stevens that she would "do whatever was required to fulfill their agreement" and asked HCFA Administrator Nancy Ann Min DeParle to oversee the PET issue directly. After several conversations and to HCFA's credit, a new payment policy of $1,980 per PET scan was established.

The Status of PET Today with the HCFA and the FDA

The problems of the regulatory and reimbursement issues for PET may be starting to improve. HCFA hired Jeff Kang, MD, to oversee the Medicare coverage policy for PET. Dr. Kang visited the PET Program at Duke headed by Ed Coleman, MD, and has been in contact with Coleman, Ruth Tesar, CNMT, president of the Institute for Clinical PET (ICP), Dr. Phelps, and Ken McKusick, MD, head of the Society of Nuclear Medicine's Committee on Coding and Reimbursements. Meanwhile, both Secretary Shalala and Ms. DeParle continue to believe that the agreement has been implemented and that PET scans are being paid for by Medicare for a wide range of indications. Maureen Reagan recently visited Secretary Shalala and brought up her life-saving experience with PET and the importance of PET as a clinical tool. Secretary Shalala told her that PET scans for all types of cancer were paid by Medicare. On a recent visit to her home state of Tennessee, Ms. DeParle met with Martin Sandler, MD, editor of *The Journal of Nuclear Medicine*, and his colleagues at Vanderbilt University and told them that PET had broad coverage by Medicare. The actual coverage approved by HCFA is not what Secretary Shalala and Ms. DeParle believe. The actual coverage is for a very restricted set of conditions for lung cancer (approved in January, 1998), and for a restricted set of conditions for colorectal cancer, melanoma, and lymphoma (approved in March, 1999). Further, the coverage document for lung cancer contains language intended to restrict PET's use even beyond good medical judgement, employs complicated G-codes instead of the standard CPT codes for PET, and states that "all other indications for PET have been reviewed and found not reimbursable", something that is simply not true. Broad coverage is just a dream today.

As a further example of the problems which the PET community faces today, Medicare reimbursement for a restricted set of conditions for lung cancer was approved in January, 1998. Over the last 16 months of coverage, the ICP estimates that 11,800 PET scans for lung cancer have been submitted for Medicare reimbursement, but that only about 50 % of the scans have been paid. Some institutions have been particularly hurt by the lack of payment. The Northern California PET Imaging Center in Sacramento has submitted a

total of $440,297 for reimbursement, but has received nothing so far in payment. At UCLA, claims for 180 lung cancer studies have been submitted with only 20 submissions paid so far. On average, the ICP estimates that the average time to get payment has been 9 to 12 months after submittal. Healthcare providers cannot survive when HCFA delays the payment for services this long.

Much work needs to be done with HCFA. The Medicare coverage instructions for lung cancer, colorectal cancer, melanoma, and lymphoma must be modified and simplified such that providers can productively request reimbursement and be paid in a reasonable time. The PET community has proposed new language and is working with HCFA to implement the proposed changes. The broad coverage agreement between Senator Stevens and Secretary Shalala needs to be implemented as soon as possible. (A copy of the PET community's proposed broad coverage document is attached.) A reasonanble payment procedure and period needs to be developed. We are hopeful, but skeptical due to past experiences.

On the FDA side, we have succeeded in getting legislation that requires the FDA to develop a new and unique regulatory system for PET radiopharmaceuticals. Since the passage of the FDA Reform Act, the agency has been working cooperatively with a committee headed by Jorge Barrio, PhD at UCLA, involving members of the Institute for Clinical PET (ICP), Society of Nuclear Medicine, American College of Nuclear Physicians, the Radiological Society of North America, patient advocacy groups, and industry to develop an effective regulatory framework for regulation of PET drugs. That framework is expected to be announced later in 1999 with implementation by late 2001.

The FDA appears to have also agreed to broaden the number of the PET radiopharmaceuticals approved and the scope of indications approved. The majority of PET radiopharmaceuticals listed by the U.S. Pharmacopoeia and a broad list of the indications listed earlier in this testimony will be approved by the FDA.

Conclusions and Solutions

The question presented to me by this Subcommittee was "What experiences has CTI encountered bringing positron emission tomography to market, and what incentives and barriers were created by the federal government?" Our experiences have seemed to include the full range of possibilities: business development, research, engineering, production, marketing, educational, regulatory, reimbursement, etc. The incentives and help that the federal government has provided to PET and CTI have been extensive. Over $2 billion has been invested in the leading researchers and institutions to bring PET to where it is today. The SBIR programs have provided CTI and other commercial entities with several million dollars of funds to research and develop solutions to the commercial needs of PET. Without the initial funding of the federal government, PET would have probably not developed at all. However, it seems that certain federal agencies understand and promote the importance of PET, but that other federal agencies then turn around and

create unnecessary barriers to the provision of this important technology to the public. The "left hand and the right hand" need to begin to cooperate in the use of public funds and in the full implementation of new technology to the full benefit of the American people who paid for its development.

Some solutions that I would propose for consideration by this Subcommittee as it tries to improve the process for bringing new technology to proper usage, particularly as it relates to PET and new medical technologies, include:

1. Support the Medicare broad-based coverage approvals for PET that Senator Stevens and Secretary Shalala have agreed to.

2. Change the way the CBO calculates the "cost" of a new technology or new budgetary item. Require that the "net cost" be utilized in a CBO score so that cost savings and new, improved ways of doing things are encouraged.

3. Require HCFA to be specific as to what is required for a new technology to gain Medicare approval. Currently, there are no standards for evaluating new technologies for Medicare coverage.

4. Eliminate the multiple, conflicting approval processes of the federal agencies. Both the FDA and HCFA have duplicative, oftentimes conflicting approval requirements.

5. Get more active immediately in the particular problems that the PET community is trying to overcome in gaining Medicare reimbursement. The nation's citizens are suffering needlessly, unnecessary surgeries and procedures are being performed, and billions of dollars are being wasted.

Thank you for the opportunity to present this testimony before this Subcommittee. I look forward to working with you in making clinical PET a reality by bringing this important technology to the public.

Medicare Coverage Issues Manual
HCFA Pub. 6
Rev.
5/98

NEW IMPLEMENTING INSTRUCTIONS-EFFECTIVE DATE: (PET) scans for characterizing certain conditions by imaging the distribution of PET radiopharmaceuticals performed on or after January 1, 1998.

Section 50-36, Positron Emission Tomography (PET) Scans, adds new coverage of these scans for cardiac, brain and tumor imaging. Such coverage is predicated on the legal availability of PET radiopharmaceuticals for use in such scans. The existing coverage of PET with Rubidium 82 for use in imaging of the perfusion of the heart has not been changed; however, the section has been extensively re-written to accommodate the addition to coverage of new uses of PET.

50-36 POSITRON EMISSION TOMOGRAPHY SCANS

I. General Description

PET is a noninvasive imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. Images are obtained from positron-emitting radioactive tracer substances (radiopharmaceuticals) that are usually administered intravenously to the patient.

PET is a useful diagnostic imaging modality for characterizing of tumors, cardiac disorders and neurologic disorders differently than anatomic imaging modalities such as CT and MRI. Certain diseases cause abnormalities of blood flow or metabolism before anatomic changes are apparent, and these diseases can be detected by PET at a time when the anatomic imaging studies are normal. PET can evaluate tissue metabolism to determine the presence or absence of malignancy whereas anatomic imaging depends on size of lesions in certain locations to determine the likelihood of malignancy. Scar tissue is not metabolically active, whereas ischemic myocardial tissue and malignant tissue are metabolically active. The use of PET in detecting and staging multiple malignancies, characterizing myocardial blood flow, identifying viable myocardium that improves in function with revascularization, identifying a seizure focus, grading the degree of malignancy in brain tumors, differentiating necrosis from persistent tumor after brain tumor therapy, identifying the abnormality of Alzheimer's and differentiating it from other causes of dementia, and identifying the metabolic abnormality of movement disorders, has been established in medical practice.

II. Conditions Applicable to all Covered Uses of PET Scans:

Regardless of any other terms or conditions, all uses of PET scans, in order to be covered by the Medicare Program, must meet the following conditions:

1. Such scans must be performed using either PET scanners that have been approved and cleared for marketing by the FDA as PET scanners or gamma camera Systems that are marketed with FDA clearance for both single-photon and PET imaging. Medicare contractors will determine, prior to making payment, that the center applying for payment has used either an FDA PET scanner or gamma camera system that is marketed and FDA approved for both single-photon and PET imaging in the performance of the scan for which payment is being claimed.

2. Submission of claims for payment must include any Information Medicare requires to assure that the PET scans performed were: (a) medically necessary; and (b) used PET radiopharmaceuticals which are legally available pursuant to Section 121 of the Food and Drug Administration Modernization act of 1997.

III. Coverage of PET Scans Using Rubidium-82 (Rb-82) and Related Tests Effective for Services Performed on or After March 14, 1995:

PET scans done at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium-82 (Rb-82) are covered, provided such scans meet either one of the two following conditions.

1. The PET scan, whether rest alone, or rest with stress, is used in place of, but not in addition to, a single photon emission computed tomography (SPECT); or

2. The PET scan, whether rest alone or with stress, is used following a SPECT that was found inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of these requirements, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data).

NOTE: PET scans using Rubidium 82, whether rest or stress are not covered by Medicare for routine screening of asymptomatic patients, regardless of the level of risk factors applicable to such patients.

IV. Coverage of PET Scans Using PET Radiopharmaceuticals - Effective for Services Performed on or after January 1, 1998:

Background: Some uses of PET imaging are still considered investigational, but PET is

considered medically efficacious for several uses. The following descriptions are general guidelines and examples of the uses to be covered rather than a restrictive list of specific coverages. As with all items and services, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

1. Coverage of PET scans for imaging cancer patients.

   Lung carcinoma - to differentiate benign from malignant solitary pulmonary nodules, to stage mediastinal and distant disease, and to monitor effectiveness of therapy.

   Colorectal carcinoma - to detect recurrent colorectal carcinoma, to distinguish recurrent tumor from scar, and to stage patients with advanced disease.

   Head and neck tumors - to detect primary head and neck tumors, to differentiate scar from tumor after therapy, and to detect metastatic disease.

   Lymphoma - to detect and stage Hodgkin's and non-Hodgkin's lymphoma and to monitor response to therapy.

   Malignant melanoma - to detect and stage malignant melanoma and to monitor response to therapy.

   Hepatic carcinoma - to detect hepatic cancers and to monitor therapy.

   Ovarian carcinoma - to detect and stage ovarian carcinoma and to assess response to therapy.

   Breast carcinoma - to detect primary breast cancer in patients with breasts difficult to evaluate with mammography or breasts with implants, to determine the extent of disease in patients with breast cancer, and to monitor effectiveness of therapy.

   Pancreatic carcinoma - to detect and stage pancreatic carcinoma.

   Thyroid carcinoma - to image metastases of advanced thyroid carcinoma.

   Musculoskeletal tumors - to detect primary and recurrent or residual musculoskeletal tumors and to monitor response to therapy.

2. Coverage of PET scans for characterizing myocardial blood flow and viability.

Coronary artery disease assessment - to detect coronary artery disease and to identify individual stenosed vessels from studies performed both at rest and during stress.

Treatment of coronary artery disease - to identify changes in blood flow following angioplasty or coronary artery bypass grafting or pharmacologic interventions (for example, cholesterol lowering drugs.)

Myocardial viability - to assess potential reversibility of an impairment in cardiac wall motion or left ventricular function for revascularization in chronic coronary artery disease.

Acute myocardial infarction - to assess location and severity of myocardial infarction, benefit or thrombolytic therapy, need for mechanical revascularization and potential for salvaging injured myocardium.

Assessment of risk for cardiac morbidity and mortality.

3. Coverage of PET scans for brain imaging in various physiological and pathologic conditions:

Brain tumor - to grade the degree of malignancy and to differentiate necrosis from persistent tumor after therapy.

Seizure disorder - to determine sites of epileptogenic foci in patients with partial complex seizure disorder refractory to medication.

Dementia - to characterize etiological cause of dementia and to differentiate dementia of the Alzheimer's type from other causes of dementia.

Stroke - to determine the degree and extent of brain damage.

Mental depression - to differentiate unipolar from bipolar depression and to differentiate chronic depression from Alzheimer’s disease.

Behavior-metabolism relationship studies - to delineate normal function or deficits in specific brain function.

Movement disorders - to differentiate movement disorder and assess response to medical and surgical therapy.